No. 04-1084

In The

Supreme Court of the United States

ALBERTO R. GONZALES,
ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

O CENTRO ESPIRITA BENEFICIENTE
UNIAO DO VEGETAL, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

BRIEF FOR DR. JOHN H. HALPERN, DR. JUAN SANCHEZ-RAMOS, AND PROF. JIMMY GURULE, AS AMICI CURIAE SUPPORTING RESPONDENTS

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INTEREST OF THE AMICI CURIAE[1]

Dr. John H. Halpern

Dr. John H. Halpern is Associate Director of Substance Abuse Research of the Biological Psychiatry Laboratory, a unit of the Alcohol and Drug Abuse Research Center at the McLean Hospital, an affiliate of the Harvard Medical School. McLean maintains the world's largest psychiatric research program in a private hospital; the Center conducts multidisciplinary research on the behavioral and biological aspects of substance abuse. Goals of this research program are to improve understanding of the multiple determinants of drug abuse and alcoholism, to develop more effective treatment and prevention programs, and to gain a better understanding of the use of controlled substances in therapy and as religious sacraments.

Dr. Halpern has been studying various aspects of the use and abuse of controlled substances under grants from Harvard Medical School, the National Institute on Drug Abuse, and private foundations. Dr. Halpern has just completed a major study on religious use of peyote, to be published in the journal *Biological Psychiatry*.[2] This study was discussed at trial and is the only study conducted in the United States that bears directly on issues in this litigation.[3]

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[1] No counsel for any party has authored this brief in whole or in part and no person or entity, other than amicus or its counsel, made any monetary contribution to the preparation or submission of this brief.

[2] J.H. Halpern, A.R. Sherwood, J.I. Hudson, D. Yurgelun-Todd, & H.G. Pope, Jr., *Psychological and Cognitive Consequences of Long-Term Peyote Use Among Native Americans* (forthcoming). An abstract is available at http://journals.elsevierhealth.com/periodicals/bps/content/59434abs.

[3] Plaintiffs' expert Dr. Charles Grob referred to Dr. Halpern's study on several occasions. Jt. App. 618-19, Tr. 226-27, 241-43. The safe and beneficial use of peyote in a religious context supports plaintiffs' position that there are no public health issues associated with the use of hoasca. *See* Tr. at 277 *et. seq.* Dr. Herbert Kleber, former Director of the Office of National Drug Control Policy during the administration of George H.W.

(Continued on following page)

Dr. Juan Sanchez-Ramos

Dr. Juan Sanchez-Ramos is Professor of Neurology, Pharmacology, and Psychiatry in the University of South Florida College of Medicine. He has had a long career bridging basic research in neurotoxicology with clinical research in movement disorders. He became interested in beta-carbolines as potential therapeutic agents for Parkinson's Disease after reading a 1928 article by Lewis Lewin on the use of a *banisteriopsis*-derived alkaloid to treat post-enceophalatic parkinsonism. Dr. Sanchez-Ramos's interest in this substance led to his further review of the uses of ayahuasca.[4] He has noted that no long term deleterious effects on the nervous system has been reported in chronic users of these substances by members of churches who routinely use hoasca as a sacrament. A double-blind study conducted with a colleague in Ecuador demonstrated that extracts prepared from the *banisteriopsis* vine (excluding the *psychotria viridis* plant, the source of DMT in hoasca) relieved slowness and rigidity in Parkinson's patients. As a translational neuroscientist, Dr. Sanchez-Ramos seeks to apply basic research findings to clinical applications, without overlooking the importance of potential neurotoxicity.

Prof. Jimmy Gurule

Prof. Jimmy Gurule is Professor of Law at Notre Dame Law School with long experience, both scholarly and

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Bush, stated: "However, the current position that permits bone fide members of the Native American Church to use peyote in a controlled, communitarian setting may serve as a useful model and could be expanded." Tr. at 293. This testimony directly supports amici's argument that the peyote model applies directly to the UDV's sacramental use of the hoasca tea.

[4] "Ayahuasca" is sometimes used as a synonym for hoasca; more often, it is used as a more generic word for hoasca and similar teas brewed from Amazonian plants.

practical, in the study of drugs and drug enforcement. He has served as Deputy Chief of the Major Narcotics Section in the U.S. Attorney's Office in Los Angeles (1985-89), as Assistant Attorney General, Office of Justice Programs (1990-92), and as Under Secretary for Enforcement, U.S. Department of the Treasury (2001-03).[5] His books include *Complex Criminal Litigation: Prosecuting Drug Enterprises and Organized Crime* (Michie 1996), *The Law of Asset Forfeiture* (Lexis Publ. 1998) (providing a comprehensive analysis of the federal drug forfeiture laws), and *International Criminal Law: Cases and Materials* (Carolina Academic Press 2000) (co-authored). His work in the field has been recognized by the Treasury Medal (2003), the Attorney General's Distinguished Service Award (1990), and the Drug Enforcement Administration's highest award, the Administrator's Award (1990).

Amici urge that in the quest to protect the public health from abuse of dangerous drugs, it is important that health professionals and law enforcement rely on available research and not on knee-jerk reactions. Much of that research is in the record in this case and supports the judgment of the courts below. Additional scholarly research is cited in this brief.

SUMMARY OF ARGUMENT

Psychotria viridis is a small plant containing the Schedule 1 hallucinogen N,N-5,5-dimethyltryptamine (DMT). Numerous other trees, shrubs, and plants found in the Western Hemisphere (including the United States) contain more than just trace amounts of DMT. Some of these are also used ceremonially, but not by the Brazilian religion at issue in this case. None of these other plant species are listed by the DEA as "controlled substances."

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[5] In this position, he held oversight responsibility for the U.S. Customs Services, a defendant in this case.

DMT is not orally absorbed (and therefore not psychoactive) unless a gut-lining enzyme, monoamine oxidase (MAO), is destroyed or temporarily inactivated. *Banisteriopsis caapi* is a large, rugged vine containing three chemical alkaloids not listed in any Schedule of the Controlled Substances Act of 1970. These three alkaloids of the *B. caapi* vine all possess reversible time-limited MAO inhibition, thereby permitting DMT to be absorbed into the bloodstream. The two plants taken in combination, as in the typical hoasca brew, induce a psychoactive effect as increasing MAO inhibition enables more remaining DMT to be absorbed through the gastrointestinal tract. With the first ingestion, effects often occur within the first hour and then gradually subside over the next 2 to 4 hours.

Neither *Banisteriopsis caapi* nor *Psychotria viridis* nor the scores of other plants, trees, and shrubs that contain traces of DMT, are controlled under the Controlled Substances Act (CSA). Despite this fact, the Department of Justice is treating the sacramental ingestion of the tea as though it were a criminal offense, erroneously concluding that the CSA prohibits the import and ingestion of the tea simply because it contains trace amounts of DMT.

The Controlled Substances Act of 1970, 21 U.S.C. § 811 *et seq.*, separately lists controlled substances and plants that contain controlled substances. The United Nations Convention[6] also distinguishes between controlled substances and plants that contain controlled substances. Not all plants containing controlled substances are regulated by the CSA or by the Convention.

Neither the plants used to make sacramental hoasca tea, nor the tea itself, is listed under the CSA or the Convention. The CSA and the Convention regulate only the synthetic form of DMT. They do not regulate trace

[6] United Nations Convention on Psychotropic Substances, Vienna, Austria, opened for signature Feb. 21, 1971 ("Convention").

amounts of naturally occurring DMT found in the hoasca tea used for sacramental purposes.

The only evidence presented to Congress when DMT was listed as a drug to be regulated under the CSA involved the synthetic form of DMT. No evidence was presented suggesting that trace amounts of naturally occurring DMT found in hoasca tea (or the plants from which the tea is made) are dangerous or should be regulated in any way.

Tribunals in other countries have concluded that sacramental uses of plants containing naturally occurring DMT, as well as sacramental teas made from those plants, are not regulated by drug laws. The United Nations has determined that the Convention does not apply to plants containing naturally occurring DMT, or to teas made from those plants. The Oregon Board of Pharmacy also has concluded, after conducting a factual inquiry and holding a public hearing, that sacred use of a similar tea containing trace amounts of DMT is not a "controlled substance."

The district court held that the Convention does not apply to hoasca tea, but that the CSA does apply. The court's opinion is puzzling. The court found "persuasive" the argument that principles of statutory construction suggest that hoasca is not regulated by the CSA, Pet. App. 200a, but then held that the CSA applies to hoasca according to the CSA's "plain language." *Id.* at 203a. The district court then held that the Convention, which has language identical to the CSA language that the court found unambiguous, does *not* apply to hoasca. *Id.* at 242a. The district court's inconsistent interpretations of the parallel language of the CSA and the Convention provide compelling evidence that statutory language of the CSA is, in fact, ambiguous.

The government's post hoc attempts to articulate a compelling government interest are without merit. The government cites no fact investigation by any federal agency into whether sacramental use of hoasca creates a compelling government interest.

There are no known reports of ayahuasca in general, or the hoasca tea in particular, being a cause of either short term toxic effects or long term neurocognitive deficits of any kind. Human dose-response studies have been performed with synthetic DMT, and some neuropsychological, anthropological, and neuroendocrine studies have been conducted with members of the UDV. These early studies, described by Dr. Charles Grob in his Declaration and at trial, conclude that DMT can safely be administered in a religious setting and that hoasca drinkers appear healthy and neurocognitively intact. Amici's experience studying ayahausca and peyote supports the conclusions of Dr. Grob. Thus the government has failed to establish in the record any compelling public health related problems that could justify criminalizing the tea as used in the UDV religious practices.

ARGUMENT

I. THE HOASCA TEA AND THE PLANTS FROM WHICH IT IS MADE ARE NOT REGULATED.

Although the district court ultimately found that the CSA regulates hoasca, the court found "persuasive" the UDV's arguments that principles of statutory construction suggest that hoasca is *not* regulated by the CSA. Petitioners' brief ignores the fact that the CSA separately lists controlled substances and plants containing controlled substances. Neither of the plants used to make hoasca is listed under the CSA, and hoasca itself is not listed.

A. The Controlled Substances Act Does Not Apply.

Petitioners erroneously assume that *all* materials containing *any* amount of a controlled substance are automatically "scheduled" and thus illegal under the CSA. This is simply not true. Had either Congress or the Drug

Enforcement Administration intended to control both DMT and the plants in which DMT naturally occurs, they could have expressly listed both the chemical substance and the plants containing the substance, as Congress has done with respect to other controlled substances and associated plants.

Mescaline (the principle psychoactive alkaloid), and peyote (the plant that contains mescaline) are listed separately. *See* 21 U.S.C. § 812(c), Schedule I(c)(11) (Mescaline) and (12) (Peyote). Several cactus species contain mescaline, but only one, *Lophophora williamsii* (peyote), is scheduled. The other species are legal and commonly sold in many nurseries.

Virtually all Morning Glory plant seeds, especially *Ipomoea violacea*, contain some amount of lysergic acid amide, a scheduled controlled substance, but the plants are not scheduled and the seeds are sold legally without restriction throughout the United States. Common poppy seeds are sold legally everywhere in the United States, even though they contain trace amounts of the controlled substance opium.

The treatment of DMT and hoasca parallels these examples. DMT is scheduled (*see* 21 U.S.C. § 812(c), Schedule I(c)(6)), but *psychotria viridis* leaf, the plant containing trace amounts of naturally occurring DMT that is used to make the hoasca tea, has never been scheduled. *Psychotria viridis* can be purchased legally, despite the fact that it contains DMT.

In 1968 the Commissioner of the Food and Drug Administration, during testimony on the dangers of hallucinogens, provided a chart listing "laboratory seizures" of DMT and LSD.[7] His description of the DMT

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[7] *See* Statement of James Goddard, *Increased Controls Over Hallucinogens and Other Dangerous Drugs: Hearing Before the Subcomm. on Public Health of the Comm. on Interstate and Foreign Commerce*, 90th Congress 68 (1968).

"dosage form" is consistent with synthetic DMT. He mentioned "intramuscular" (*i.e.*, injected) delivery and "inhalation," but said nothing about oral ingestion in any plant form.[8] DMT was described elsewhere in the legislative history as "a relatively new *synthetic*."[9]

Synthetic DMT is a drug with a "high potential for abuse" and with some scientific evidence at the time of scheduling to support its being listed on Schedule I. But, there is no evidence that the hoasca tea is a "substance" with a high potential for abuse, and thus it appropriately was never listed. Congress has never considered either *psychotria viridis* or any other plant or plant material in which DMT is found, never made findings about them, and never scheduled them as a controlled substance. Moreover, amici would not be able to identify any reputable drug and alcohol research component of a psychiatric hospital or university in the United States that would argue that a nonlisted plant such as *psychotria viridis* is a controlled substance.

The district court found that the CSA unambiguously applies to hoasca, because Schedule I(c), the schedule on which DMT is listed, provides that "'[u]nless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances falls within the Schedule I category." Pet. App. 198a. The district court concluded that Congress must have intended that hoasca be considered a "material, compound, mixture, or preparation" within the meaning of the CSA. *Id.*

The district court's conclusion that this language is unambiguous failed to account for the fact that the CSA distinguishes between "a drug or other substance." 21

[8] *Id.* at 76.

[9] *Id.* at 197, reprinting Council on Mental Health and Comm'n on Alcoholism and Drug Dependence, *Dependence on LSD and Other Hallucinogenic Drugs*, J. Am. Med. Ass'n (Oct. 2, 1967).

U.S.C. § 812(b). The CSA's distinction between "drugs" and "other substances" anticipates that "other substances" will be listed separately should Congress or the Attorney General conclude that "other substances" meet the criteria for being placed on the schedule. Peyote, for example, is not a "drug," but it is an "other substance" listed under the CSA. Marijuana also is not a "drug," but is an "other substance" listed under the CSA. *See* 21 U.S.C. § 812(c), Schedule I(c)(10). If the reference to "any material, compound, mixture, or preparation" were as unambiguous and broad as the district court held, the separate listing of peyote and marijuana would be superfluous.

What Congress meant by the terms "material, compound, mixture or preparation" in the context of the CSA is a "carrier medium" created to facilitate commercial delivery of a drug.[10] *See Chapman v. United States*, 500 U.S. 453, 461 (1991) (blotter paper containing LSD is a "mixture"). The Court in *Chapman* acknowledged that the term "mixture" is not defined in the CSA, and has no established common law meaning. *Id.* at 462. The Court therefore applied a dictionary definition to the term. *Id.* The fact that the word is capable of different definitions, depending upon context (as implicitly recognized in *Chapman*), refutes the district court's conclusion that the word is unambiguous.[11]

This Court's opinion in *Chapman* treated a "mixture" as a combination of a listed drug with a "dilutant, cutting

[10] Carrier mediums are fairly common, and drug and alcohol researchers understand that those terms were meant to convey to illicit drug users that they would be held accountable regardless of the medium within which they attempted to transport the drug.

[11] The Court's reasoning does not apply to simply brewing a plant as a tea. *Chapman* suggests that if the DMT were extracted from the tea in sufficient quantities and then, in its pure form, placed on a blotter and was absorbed by the blotter, it might be a "mixture." It would take an enormous amount of the *Psychotria viridis* leaf to do that, and then it would not be active when taken orally.

agent, or carrier medium" designed to make the listed drug more transportable, salable, or usable. *Id.* at 460. In every case discussed in *Chapman*, a supplier started with what was unambiguously a listed drug; the supplier intentionally mixed that drug with the dilutant, cutting agent, or carrier medium; and the drug did not lose its identity in the resulting mixture. The mixture was "a tool of the trade for those who traffic in the drug." *Id.* at 466.

In this case, no one started with DMT and mixed it with a dilutant, cutting agent, or carrier medium. And at no stage in the process of brewing hoasca is DMT ever distilled out or otherwise separated from the other substances in the plant. The district court found "that hoasca is clearly distinct from DMT, just as *psychotria viridis* is, and that there are no indications that the tea-making process produces a chemical separation of DMT." Pet. App. 242a.[12] Instead, those producing hoasca work with two naturally occurring plants, neither of which is a listed drug. The result is not a "mixture" as that term is used in *Chapman*. If hoasca is a mixture, then poppy seeds and morning glory seeds and numerous cacti are also mixtures.

Chapman thus highlights the essential ambiguity that petitioners refuse to acknowledge. "Preparation" or "mixture" means the result of a person starting with the scheduled substance and preparing it for sale or mixing it with other substances. Petitioners read these terms as including any naturally occurring mixture that contains a scheduled substance, even if no human being mixed the various components of the naturally occurring mixture. The choice between these interpretations is inherently ambiguous. Legislative history, judicial interpretation in

[12] The quoted passage comes from a passage stating plaintiffs' argument on the Convention. Immediately below, the court adopted plaintiffs' argument as its own. "Based on the analysis offered by the Plaintiffs, this Court finds that the 1971 Convention on Psychotropic Substances does not apply to the hoasca tea used by the UDV." Pet. App. 242a.

Chapman, common understanding among drug scholars, and international interpretation of parallel provisions in the UN Convention all support the view that mixture or preparation means a man-made mixture that starts with the scheduled substance – not with a naturally occurring substance from which the scheduled substance is never separated.

The government argued below that "[i]t is far more likely that Congress listed those plants of which it was aware, and left others for inclusion under the expansive language "'any material.'"[13] Opposition to Motion for Preliminary Injunction 10. This fails to explain why Congress and the DEA needed to list *any* plants if all plants containing any amount of a controlled substance were automatically included. It also assumes much that is not in the record. It assumes that Congress was not aware that poppy seeds contain opium or that a myriad of other plants sold in stores all across America contain scheduled substances. And the claim that Congress had never heard of these plants is fatal to another of the government's claims – that Congress made informed findings about the dangers of hoasca, and that this Court should defer to those findings. If Congress had never heard of the plant, the tea, or the religion, it obviously made no findings concerning the dangers of the plant, the tea, or controlled religious use.[14]

[13] This is directly contrary to the government's assertion on page 11 of the same document that Congress specifically *excluded* the *Psychotria viridis* leaf. *Chapman* did not address the word "material," but that word is at least as ambiguous as "mixture."

[14] In fact, the decisions Congress did make in listing DMT and other drugs were not informed by any serious investigation or findings. At the time of scheduling in 1970, Congress had not actually undertaken a review of DMT to determine if it is a substance with a "high potential for abuse." Testimony given at a CSA scheduling hearing recommended that DMT was more appropriately listed as a Schedule II substance. Dr. Leo Hollister of the Veterans Administration testified:

(Continued on following page)

RFRA (which was not at issue in *Chapman*) requires that ambiguous terms be interpreted in a way that does not burden religious practices unless there is a "compelling interest" in doing so. As other tribunals have held, the terms "material, compound, mixture or preparation," do not even include hoasca. *See In the Matter of Bauchet*, Case No. 04/01888 (Paris Ct. App. 2005), Opp. Cert. App. 67, 93-94; Letter from Herbert Schaepe, Sec. Int'l Narcotics Control Bd., Opp. Cert. App. 51, 51-52.

Petitioners argued in the district court that "another reason why some plants, and not others, *might* be listed separately under Schedule I is that the Single Convention on Narcotic Substances affirmatively required Congress to list certain plants." Opposition at 11 (emphasis added). The government offers no evidence to support this conjecture. A number of scheduled plants, including peyote, are scheduled in the CSA but not identified in the Single Convention on Narcotic Substances, so this cannot explain the existence of a separate list of regulated plants.

The Petitioners, below, offered the novel theory that "[t]he plants listed under Schedule I are controlled regardless of whether they contain the chemical hallucinogenic in question." Opposition at 11. The government cites nothing in the legislative history to support this speculation. And it cites no evidence whatever that some individual peyote or

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> I have been unable to find any scientific colleague who agrees that the scheduling of drugs in the proposed legislation makes any sense, nor have I been able to find anyone who was consulted about the proposed scheduling. This unfortunate scheduling, which groups together such diverse drugs as heroin, LSD and marijuana, perpetuates a fallacy long apparent to our youth. These drugs are not equivalent in pharmacological effects or in the degree of danger they present to individuals and to society.

Statement of Leo E. Hollister, M.D., *Drug Abuse Control Amendments: 1970 Hearings Before the Subcommittee on Public Health and Welfare*, 91st Cong. 747-51 (1970). Dr. Hollister was Associate Chief of Staff of the VA Hospital in Palo Alto, California.

marijuana or other listed plants fail to contain the chemicals that are identifying traits of their species. The government did cite *United States v. Coslet,* 987 F.2d 1493, 1496 (10th Cir. 1993). But the issue in *Coslet* was not whether some of the plants at issue were marijuana plants that failed to contain the psychoactive chemical, THC. The issue in *Coslet* was defendant's claim that "the prosecution failed to establish that at least 100 of the plants discovered at the field were marijuana plants." *Id.* The court held that not all plants had to be tested where the agents visually identified all the plants and where that identification was confirmed by testing of a random sample. *Id.* at 1496-97.

The CSA was promulgated to prohibit the trafficking in "drugs," not in plants that do not contain drugs. The plants listed on Schedule I are listed *because* they contain drugs, not *regardless* of whether they contain drugs. Of course the logical explanation in this case is the correct one – Congress separately listed those plants that it wished to regulate and it had no intention of regulating plants that it did not list.

21 U.S.C. § 811(c) provides:

> [T]he Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled *or removed* from the schedules: (emphasis added).[15]

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[15] The factors to be considered are:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(Continued on following page)

One can imagine asking the Attorney General to "remove" a substance (such as peyote) from the Schedule I list, because it is on the list, and to do so without removing its constituent chemical, mescaline. One cannot imagine asking the Attorney General to "remove" the *viridis* leaf from the list, because it does not even appear on the list. Petitioners are, in effect, asking this Court to judicially schedule a substance, *psychotria viridis*, bypassing the detailed substantive and procedural burdens placed on the Attorney General by the CSA.[16]

(8) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

In considering these factors, §§ 811(a) and (b) require the use of on-the-record rulemaking procedures under the Administrative Procedure Act and scientific and medical evaluation by the Secretary of Health and Human Services.

No substance may be placed on Schedule I without the following "required" findings:

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(c) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

21 U.S.C. § 812(b).

[16] To schedule the *viridis* leaf, the Attorney General must establish that it is a substance with a "high potential for abuse," and satisfy additional substantive and procedural requirements. *See* n.15 *supra*. The French government followed French rule-making procedure to separately list ayahuasca after a determination by French courts that although DMT was listed, ayahuasca was not. *See* Section I.B. of this brief.

B. The United Nations Convention On Psychotropic Substances Does Not Regulate Hoasca Or The Plants From Which Hoasca Is Made.

The district court held that the UN Convention does not prohibit the importation of hoasca. Pet. App. 242a. The court of appeals did not squarely pass on this question. Judge Seymour's opinion for a majority of the en banc court held that "for all the reasons described by the district court," that court had not abused its discretion in finding "a substantial likelihood of success on the merits." *Id.* at 71a. That opinion also held that the preliminary injunction against enforcement of the government's interpretation of the Convention would inflict little harm on the government, *id.* at 74a-75a, a ruling that also implies serious doubt about any claim of compelling interest even if the Convention did apply. Judge McConnell, concurring, noted that the district court had found the Convention inapplicable and that the government had successfully objected to evidence of the International Narcotics Control Board's interpretation of the Convention. *Id.* at 103a-104a. Then he concluded that the government had not shown that enforcement served a compelling interest by the least restrictive means "even assuming the Convention applies." *Id.* at 104a. The district court's conclusion that the Convention does not apply remains the prevailing decision below on this issue.

Petitioners concede that the Convention does not specifically list hoasca, but argue that the Convention does list DMT, and that the Convention separately provides that "'a preparation is subject to the same measures of control as the psychotropic substance which it contains'". Pet. Br. at 41-42 (quoting Art. 3, par. 1 of Convention). Petitioners then argue that a "preparation" is defined as "*any* solution or mixture, in whatever physical state, containing one or more psychotropic substances." *Id.* at 42 (quoting Art. 1(f)(1) of Convention) (emphasis added by Petitioners). Petitioners point out that this definition

"parallels the definition in the CSA that the district court unhesitatingly read to 'clearly cover hoasca.'" *Id.*

Amici agree that the district court's opinion incorrectly distinguishes between the definition in the Convention and the parallel definition in the CSA. But the district court's error was in its interpretation of the CSA, not in its interpretation of the Convention. The district court's sole reason for finding that the CSA applies to hoasca was what it viewed as the unambiguous "plain language." Pet. App. 202a. The court itself conceded that had it found the language of the CSA to be "ambiguous," statutory construction principles would "persuasive[ly]" suggest that the CSA does not apply to hoasca. *Id.* at 200a. Yet the court subsequently – and correctly – found the same language in the Convention sufficiently "ambiguous" to support reliance on authoritative interpretative materials showing that the Convention does not apply to hoasca.

For the same reasons that a "mixture" under the CSA should be interpreted to mean a deliberate mixing of a listed substance with a dilutant, cutting agent, or carrier medium, a "mixture" under the Convention should be interpreted the same way. This is the UN's official interpretation of these words in the Commentary to a subsequent treaty, *in pari materia* with the Convention:

> "Preparation," also referred to as "compounding," denotes the mixing of a given quantity of drug with one or more other substances (buffers, diluents), subsequently divided into units or packaged for therapeutic or scientific use.

Opp. Cert. App. 66. The Convention should not be interpreted to cover a tea brewed from plants, which contains small and naturally occurring amounts of a listed substance, where the listed substance never had a separate existence and was never mixed with anything. As explained *infra* with respect to the Commentary on the Convention, these official Commentaries provide authoritative guidance to the meaning of UN Conventions.

The Senate's understanding of the Convention at the time of ratification was that the Convention did not currently apply to plants that contain listed substances. Sen. Exec. Rpt. No. 96-29, *Convention on Psychotropic Substances*, 96th Cong., 2d Sess. 4 (1980), quoted in Pet. App. 240a.

Similarly the official United Nations Commentary on the Convention on Psychotropic Substances, published simultaneously with the effective date of the Convention, states that the Convention does not apply to plants or to "infusions" or "beverages" made from plants. Opp. Cert. App. 58, quoted in Pet. App. 241a-242a. This Commentary "is an official document and provides authoritative guidance to Parties in meeting their obligations under the Conventions." Declaration of Herbert S. Okun, Opp. Cert. App. 48 par. 5. Mr. Okun served for ten years as the United States member of the United Nations International Narcotics Control Board (INCB). *Id.* at 47, par. 1. The Commentary is further confirmed by official advice issued in 2001 to the Dutch government by the INCB Secretariat, after consultation with the Scientific Section and the Legal Advisory Section of the UN International Drug Control Program:

> No plants (natural materials) containing DMT are at present controlled under the 1971 Convention on Psychotropic Substances. Consequently, preparations (e.g. decoctions) made of these plants, including ayahuasca are not under international control and, therefore, not subject to any of the articles of the 1971 Convention.

Opp. Cert. App. 52.

Most recently, there is a similar ruling from a French Court of Appeals, *In the Matter of Bauchet*, Case No. 04/01888 (Paris Ct. App. 2005), which reversed convictions for religious use of ayahuasca in France. Interpreting both the French law (which of course might be different from U.S. law) and the UN Convention (the very provisions on which the government relies here), the French Court held

that the Convention does not apply to liquids created by boiling or macerating the leaves of plants.

> [Such processes] cannot yield a "substance" in the sense *of the Vienna conventions* and French law since they do not isolate "the chemical elements and their compounds as they naturally occur or as industrially produced" . . .

Bauchet, Opp. Cert. App. 93 (emphasis added).

> Likewise, the court evidence and arguments have established that the DMT or N,N-dimethyltryptamine at issue in this case was not obtained by means of "preparation" – this being a pharmaceutical operation consisting in beforehand having the substances to be mixed or, in the case of a solution, to be dissolved in a liquid.

Id. at 94. France subsequently amended its regulations to cover the plants from which teas such as hoasca are made. Order of Apr. 20, 2005, in Pet. Br. App. 18a.[17] Similar action would be the proper course for the petitioners here. Petitioners could ask Congress to add hoasca to Schedule I. Or they could undertake the serious scientific and administrative procedures required to schedule hoasca administratively. *See* n.15 *supra*. Or if they want international regulation, they could undertake negotiations or international administrative procedures to schedule hoasca under the Convention. They have done none of those things; they have simply argued for their idiosyncratic interpretation of the Convention.

Official Commentary, official interpretation by the UN agency charged with enforcement, and judicial interpretation by another party to the Convention are in accord.

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[17] Of course the recent French *regulation* does nothing to change the authority of the French interpretation of the *Convention*. As to the Convention, the French opinion has the same legal authority in France, and the same persuasive authority here, as before the change in the French regulation.

Plants are not listed in the Convention, and teas brewed from plants are not covered by the Convention.

II. THE GOVERNMENT DOES NOT HAVE A COMPELLING INTEREST IN PROSECUTING SACRAMENTAL USES OF HOASCA.

Wrongly assuming that the CSA controls the hoasca tea, petitioners advance three arguments in support of the assertion that there is a compelling government interest in regulating its sacramental use by the UDV. One of these alleged interests is that the teas may be harmful to individuals who consume them in religious ceremonies. Pet. Br. 14-18. This health interest is within the research expertise of these amici. There is no evidence of ill health effects associated with the sacramental ingestion of the tea.

A. The Ritual Use Of Hoasca Is Distinct From Illicit Drug Use.

The UDV religion reveals a clear and consistent religious doctrine striving to promote community and family values as well as a healthy work ethic. Recreational use of hoasca is anathema to the UDV leadership, who consider the protection of hoasca for only proper sacramental purposes as one of their highest responsibilities. The use of hoasca as a holy sacrament is the central expression of religious faith for members. Religious users of hoasca come to the tea with a different preparation, different mindset, and different social surroundings from recreational users of synthetic DMT. This is a vital distinction; the consumption of hoasca as a sacrament is literally a "nondrug" use of DMT. Compare 21 C.F.R. § 1307.31 (exempting "the *nondrug* use of peyote in bona fide religious ceremonies of the Native American Church") (emphasis added).

With reference to the "concerns" expressed by Dr. Genser, the government's expert regarding neurocognitive

risks from hoasca use, it is helpful to consider similar evaluations of peyote, which Congress and the DEA have approved for religious use. Grants from the National Institute on Drug Abuse (NIDA), Harvard Medical School, and private foundations have funded amicus Halpern's study of the neurocognitive effects of lifelong ingestion of peyote by members of the Native American Church (NAC). The data show that NAC members are just as neurocognitively healthy as non-peyote using controls. Halpern, *et al.*, *supra* note 2, at 11. It is also readily apparent that the religious and visionary experiences NAC members have during the peyote ceremonies and those experienced at the UDV ceremonies cannot properly be defined as hallucinogenic intoxication. Indeed, as far back as 1966, the DEA found that taking peyote in a Native American Church service was a "nondrug use of peyote". 21 C.F.R. § 1307.31, Jt. App. 961.

The Brazilian government's report on the status of hoasca use by the UDV in Brazil reaches a conclusion that is consistent with the NIDA study by amicus Halpern regarding the positive value peyote has when used sacramentally. This government panel made the following findings regarding the Church members:

> The followers of the sects appear to be calm and happy people. Many of them attribute family reunification, regained interest in their jobs, finding themselves and God, etc., to the religion and the tea . . . The ritual use of the tea does not appear to be disruptive or to have adverse effects . . . On the contrary, it appears to orient them towards seeking social contentment in an orderly and productive manner.

Final Report of the Decisions of the Working Group Designated by CONFEN Resolution No. 4 (July 20, 1985); *see* Jt. App. 496 (summarizing this finding).

Indeed, the use of the term "hallucinogen" is both misleading and inaccurate when describing sacramental use of peyote or hoasca. The Native American Church has

over 250,000 members in the United States, Tr. 228-29, making it the largest religion among Native American peoples. Over 2 million peyote "buttons" are consumed annually in the United States through a regulated system designed in partnership between the DEA, the Texas Department of Public Safety, and the NAC. This quietly successful partnership offers positive proof that it is possible to safely regulate the wide distribution of an otherwise Schedule I substance in America when religious freedom hangs in the balance. It further proves that the government is fully capable of designing a regulatory process for the bona fide sacramental use of hoasca. Moreover, this long-standing and successful program of oversight for the distribution of peyote for the NAC proves that the government is mistaken if not disingenuous to claim that only full prohibition of sacramental hoasca is the "least restrictive means" of governmental infringement upon the religious freedoms of the UDV. According to current accounts, there are fewer than 200 members of the UDV in the United States as compared to the 250,000 peyote church members.

There are other important similarities between the religious use of hoasca and peyote. Both have thousands of years of ritual use in the Western Hemisphere. Both may induce nausea and vomiting. They have only rarely been studied and described in peer-reviewed scientific journals. There are no published reports indicating that religious use of either causes Hallucinogen Persisting Perceptual Disorder (flashbacks). There are no published reports of hoasca or peyote causing any significant medical or psychological harm to members of these religions. Hoasca has never been reported to be associated in any way with illicit drug markets. Both the leadership of the UDV and the NAC consistently state that they would inform law enforcement should they learn of any such illicit drug trafficking of their respective sacraments. These similarities may provide another layer of reassurance at the public policy level that hoasca, like peyote, appears safe for

human consumption when taken in strict accordance with bona fide, traditionally accepted religious practices.

B. The Hoasca Tea Poses No Threat To Individuals Or To Public Health.

The United States has a great tradition of providing religious freedom even when the resulting exemptions have caused "concern" amongst the traditional medical community. Thus, legislatures or courts have granted religious exemptions for refusal of vaccination,[18] treatment by faith-based healers outside allopathic medicine,[19] and refusal of blood transfusions.[20] The exemption request in this case does not raise any of the real health concerns referred to in these exemptions.

Serious medical consequences from ingestion are the rare exceptions with all hallucinogens. P.M. Carvey, *Drug Action in the Central Nervous System* 365 (Oxford Univ. Press 1998). In general these substances have a very low dependence liability. *Id.* at 366. Generally, those who oppose the religious, medical, or psychotherapeutic use of hallucinogens have incorrectly labeled them as toxic to the central nervous system and as resulting in some sort of cognitive or emotional impairment. A review of the literature in a NIDA-sponsored journal shows little or no support for these beliefs; evidence to date supports

[18] *See, e.g.*, Ga. Code Ann. § 31-35-11; R.I. Gen. Laws § 23-17.19-6(2).

[19] *See, e.g.*, 42 U.S.C. §§ 1395x(e), 1395x(y), 1395x(ss), 1395x(aaa), 1396a(a) (providing for government payment for physical care of patients in "religious nonmedical health care institutions"); *Baumgartner v. First Church of Christ, Scientist*, 490 N.E.2d 1319 (Ill. App. 1986) (no wrongful death action against church that taught patient to refuse medical care).

[20] *See, e.g., Stamford Hospital v. Vega*, 674 A.2d 821 (Conn. 1996); *Graham v. Deukmejian*, 713 F.2d 518 (9th Cir. 1983).

continued intact cognitive functioning.[21] Absent direct evidence that hoasca poses a serious health risk, which does not currently exist, there is simply no valid drug policy reason to prohibit its ingestion as a bona fide religious sacrament.

Of course there are risks associated with the ingestion of virtually every chemical substance, including those available over the counter, and particularly when they are not utilized according to directions. But thousands of substances with modest risks are legally sold in the marketplace, because modest risks do not establish any public health concern of sufficient magnitude to warrant criminalizing their use. Some risky substances are legal because their known benefits outweigh the risks; some, such as many of the largely unregulated dietary supplements, have few documented benefits but are legal because their known risks do not justify prohibition. Hoasca has substantial religious benefits for members of the UDV, and it is Congressional policy that only a compelling interest can justify taking those religious benefits away. Whatever modest risks or uncertainties may remain at the current stage of research do not remotely rise to that level.

The DEA criteria for a Schedule I drug require it to be a drug with a high potential for abuse, which the hoasca tea clearly is not. With respect to the government's concerns about diversion to illicit markets, the controls that are set forth in Judge Parker's injunction are more than adequate to prevent diversion; vastly less intrusive controls have been adequate to prevent diversion of peyote from religious use. Since the district judge has issued the preliminary injunction, there have been no reported incidents of diversion of the hoasca tea to illicit drug markets, and there are no reported problems of peyote being diverted to such markets.

[21] J.H. Halpern, & H.G. Pope Jr., *Do Hallucinogens Cause Residual Neuropsychological Toxicity?*, 53 Drug & Alcohol Dependence 247 (1999).

C. The Declarations And Testimony Of Witnesses Overwhelmingly Support UDV.

Amici first note that the methodologies utilized by Respondent's experts, Drs. Grob, Nichols, and Brito, were clearly scientifically reliable; and the conclusions are thoroughly consistent with amici's investigations of hoasca and peyote. The same cannot be said of the governments' experts. When taken in the religious context of the UDV religious services, *all* of the reliable evidence to date establishes that hoasca is a safe and positive sacrament. Moreover, both Drs. Grob and Nichols are noted international experts in the field of hallucinogen research. Drs. Grob and Nichols have many years of peer-reviewed publications concerning hallucinogens, and they continue to engage in government-funded hallucinogen-related research. The government's drug witness, Dr. Genser, testified that he had never written about hallucinogens and never researched hallucinogens. Tr. 886.

A careful review of the Declarations filed by the government witnesses, and of their testimony at trial, shows clearly that defendants have failed to rebut the reliable evidence submitted by the UDV witnesses who have made the study of the clinical effects of hallucinogens a central focus of their research endeavors.

Having little or no expertise on the subject, Dr. Genser stated: "In conclusion, given the reasonable and serious concerns about safety arising from the known pharmacological effects of the components of ayahuasca and similar compounds and given the absence of sufficient data addressing those concerns, ayahuasca cannot at this point be considered safe outside controlled research settings." The most notable thing about this conclusion is that he did *not* say that religious use of the hoasca tea is dangerous. This then is not "equipoise," but rather an absence of any credible evidence of a "compelling" reason to criminalize the tea. The "absence of sufficient data" is not a compelling interest. A religion does not have to prove that its practice is safe; under RFRA, government must prove dangers so

great that they provide a compelling reason to ban a religious practice.

Even Dr. Genser's conclusion that there are "reasonable and serious concerns" should be disregarded. As applied to the tea, there is *no* evidence that his "concerns" are more then pure speculation.

Dr. Genser's principal basis for his "serious concerns" was based upon his erroneous comparisons of the tea with LSD, which is a Schedule I hallucinogen. He also offered a digression about the serious risks of mixing serotonin specific reuptake inhibitor type antidepressants (SSRIs) with *irreversible* monoamine oxidase inhibitor type antidepressants (MAOIs). But his concerns are medically misplaced. Neither LSD nor irreversible MAOIs are found in hoasca. Yet, in a complete breakdown of the scientific method, Dr. Genser makes the rather astounding observation that it is reasonable to attribute the risk of these compounds to hoasca, apparently because the reported effects of these other compounds have been better studied. Aspirin and morphine are both analgesics. If morphine had been studied more than aspirin, no credible scientist would similarly assume that aspirin must therefore have the same risks of overdose and addiction as a powerful narcotic like morphine.

Dr. Genser's testimony that LSD has "similar compounds" to hoasca is not credible because there is absolutely no empirical data to support extrapolating risk from LSD to hoasca in a controlled religious setting. Hoasca does not contain LSD or any analog of LSD, so it is erroneous for Dr. Genser to claim that hoasca contains chemicals sufficiently similar to LSD to justify extrapolating the dangers and risks of LSD to hoasca. Moreover, LSD use, dose-for-dose, is several orders of magnitude greater than what religious practitioners consume from plant-based preparations like hoasca and the raw cactus, peyote.

Dr. Genser offered his "expertise" on a number of subjects relating to hallucinogens and was incorrect on virtually every occasion. For instance, Dr. Genser's claim

that LSD users "may suffer a devastating psychological experience, including recollections of suppressed memories, resulting in long-lasting psychosis", Jt. App. 125, reveals that he ignores the importance of the set and setting within which the sacramental ingestion of the tea takes place. Dr. Genser's testimony exaggerates and misstates the etiology of psychotic disorders. The religious contexts in which the hoasca is taken militate against the "possibility" of a negative reaction. Dr. Genser's speculation of a "devastating psychological experience" has absolutely no empirical foundation as it applies to the hoasca experience.

Rather than provide reliable data, Dr. Genser engaged in outright fear mongering by suggesting that chronic psychotic illnesses can be directly attributable to hallucinogenic use. There is simply no evidence in the scientific journals to support this speculation. The prevalence of psychotic illnesses in the United States remains consistent with the prevalence of such illness in the rest of the world: approximately one percent of all people are afflicted with chronic psychotic illnesses. More tellingly, schizophrenia has not increased in numbers since hallucinogen abuse became a public health concern starting in the late 1960s.

Amici are unaware of any studies that identify "devastating psychological experience(s)" or the "recollection of suppressed memories" as an essential ingredient in the induction of "long-lasting psychosis."[22] The only study cited by Dr. Genser lumped together eleven users of "hallucinogens, amphetamines, and inhalants" in a single class labeled "psychostimulants."[23] It is impossible to measure

[22] Dr. Genser attempted to create an inference that because LSD can cause "persisting perceptual disorder known as flashbacks," flashbacks were also a valid concern about ritual use of hoasca. Tr. 833. But on cross-examination, he admitted that "there is no evidence that DMT will produce [that] syndrome . . . " *Id.* at 889.

[23] A. Thomas McLellan, George E. Woody, & Charles P. O'Brien, *Development of Psychiatric Illness in Drug Abusers*, 301 New England

(Continued on following page)

any effect attributable to hallucinogens from this study. The only evidence in this study that tends to distinguish hallucinogens from other drugs also tends to refute Dr. Genser's claim: over time, as amphetamine use increased and hallucinogen use decreased, psychological symptoms increased sharply in variety and intensity.[24]

Dr. Genser was wrong again when he stated that "[p]ost-LSD psychoses resemble schizoaffective disorders, and are frequently accompanied by visual disturbances." Jt. App. 125. Prolonged adverse reactions to hallucinogens are rare. Amici are unaware of any studies or psychiatric textbooks that describe the existence of an LSD-induced persistent psychosis as "schizoaffective" with "visual disturbances." Dr. Genser never explained how he arrived at this conclusion. His conclusion is outside the scope of his expertise and outside the mainstream of drug abuse research. It is an untenable hypothesis to suggest that an individual may suffer a lifetime of schizophrenia from the single use of an hallucinogen in the absence of other more serious risk-factors. There is nothing in the medical literature to support Dr. Genser's contrary speculation.

There *is* evidence contrary to Dr. Genser's speculation. In a long-term study of cognitive and psychological effects of chronic peyote use, which included interviews of hundreds of members of the Native American Church who use peyote as their religious sacrament, none of the interviewees ever complained of episodes of flashbacks when asked. Halpern *et al.*, *supra* note 2. Peyote is not identical to hoasca, but it is similar, and more important, the set and setting of its religious use is very similar to the set and setting of religious use of hoasca. The set and setting make this study far more relevant to this case than any study of recreational drug abusers.

J. Med. 1310, 1310 (1979). All eleven study subjects were drug abusers, *id.*; controlled use in a religious set or setting was not part of the study.

[24] *Id.* at 1311.

While Dr. Genser concludes that hoasca is too dangerous to be "'considered safe outside controlled research settings,'" he neglects to consider that these research settings may today be less safe than the religious settings of the UDV or NAC. Given the paucity of active research on hallucinogens, other than amici and several experts who testified for the UDV, controlled research settings may have something to learn from the long-standing, well-practiced, and carefully controlled rituals of these religions. These religions have leaders with tremendous experience with their sacrament's effects upon people, and traditions have been handed down over generations to promote safety and deepen religious values. The screening, preparation, and supportive measures (pre-, post-, and in-session) for members of the UDV are carefully designed to protect and promote wellbeing and should not be dismissed, a priori, as being uncontrolled. Reassuringly, the safety measures implemented by these religions appear to also have much in common with the safety measures implemented in past clinical research, such as creating a supportive environment with nurturing attendants readily at hand. The specter of serious consequences invoked by Dr. Genser is based solely on the dangers of hallucinogen use in uncontrolled settings and on his non-scientific speculations.

With over 100 years of religious tradition and actively practiced faith in the United States, the current 250,000 members of the Native American Church continue to ingest peyote as their sacrament in controlled religious settings outside the "safety" offered by "controlled research settings." The extensive research to date establishes that none of the "concerns" of Dr. Genser appear to have actually manifested in the largest relevant population of Americans religiously employing an hallucinogen as their sacrament in a religious ceremony. Nor does the record reflect any evidence for Dr. Genser's "concerns" arising from the vast number of sacramentally administered doses of hoasca in Brazil.

There has simply been no demonstration of a public health risk associated with the religious use of the UDV tea. When Dr. Genser's concerns are carefully scrutinized, it is clear that there are no compelling government health or drug-policy interests sufficient to justify preventing the free exercise of the UDV's religion in the United States.

While the district judge seems to have been gracious toward the government in describing the health-related evidence as being in "equipoise," amici's review of the evidence as set forth above establishes beyond scientific question that the evidence was *not* in "equipoise," but tipped decidedly in favor of the UDV's position. The testimony of government witnesses was either incorrect medically or was gross speculation about the "possible" consequences of taking the tea as a sacrament. The government is offering only "concerns" as a substitute for data.

It is important from a drug policy perspective that the government be required to follow the scientific procedures established by Congress in the Controlled Substances Act for listing drugs in the first instance. In this regard, amici points out that the government has not engaged in any of those procedures to attempt to list the hoasca tea or its component parts or the plants from which it is made. Amici urge upon this Court the belief that the government must utilize the existing CSA regulatory scheme to try to list hoasca tea if it truly believes it to be a public health menace.

The government's position that federal courts are ill-equipped to decide such issues is just grandstanding. Federal courts are equipped to decide much more complicated scientific issues then those presented in this case. It is this oversight by federal courts that can force government agencies such as the DEA to operate within the laws established by Congress and informed by reliable science.

CONCLUSION

The Court can decide this case on the interpretive ground that neither the CSA nor the Convention apply to hoasca or the plants from which it is made. There is no need to decide issues of RFRA, compelling interest, or the government's reliance on junk science. But these issues go hand in hand. The tea is not controlled under the CSA or the Convention for the very good reason that it does not pose any significant public health problem.

The preliminary injunction should be affirmed.

Respectfully submitted,

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